Fact Sheet

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BIOTECHNOLOGY: RESHAPING GLOBAL AGRICULTURAL MARKETS

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An Interview With Timothy J. Galvin,
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Advances in the use of agricultural biotechnology in food production have become sweeping economic and trade policy issues in the last half of this decade, forcing governments to rethink how to manage trade and at the same time ensure food safety. The United States is not alone in developing new genetically modified organism (GMO) products or in offering them for commercial production. There have been GM varieties planted in a number of countries -- the United States, Argentina, Canada, Australia, Spain, France, and others. And even in the United States, it is not just U.S. companies that are involved in the field; some European Union companies have also developed a substantial presence.

In this interview, FAS Administrator Timothy Galvin discusses some of the central issues confronting the United States and many of its trading partners worldwide. This interview was conducted by ***Economic Perspectives*** *editors Jonathan Schaffer and Merle D. Kellerhals, Jr.*

QUESTION: Food production enhanced through the application of agricultural biotechnology has been touted as producing greater yields. Beyond that, how do consumers directly benefit from biotech products?

GALVIN: With this first generation of biotech products on the market, the public benefits from the potential for reduced pesticide use. And, of course, if there is reduced pesticide use then there is probably less pesticide in the final commodity and there is also less potential for

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the pesticide chemicals leeching into groundwater. So I think consumers benefit from the fact that there is a cleaner environment. However, a number of people are looking forward to the so-called second generation of biotech products because those products are likely to have end-use characteristics that directly benefit consumers, such as agricultural commodities that have a higher vitamin content, or iron content, or perhaps reduced fat levels.

Some of the most exciting agricultural research currently is happening in the area of rice. There has been a lot of discussion this summer about progress with biotech rice varieties. Those

varieties have higher iron and vitamin content. And it is thought that they could be grown easily and at a relatively low cost by even the smallest subsistence farmers.

Q: There has been some criticism that the U.S. regulatory process established specifically for biotechnology products is not adequate to provide for the protection of human health and the environment. How do you respond to the safety issue?

GALVIN: Three different regulatory agencies in the United States typically are involved in approving these products -- the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), if it's a food or animal feed product, and the Environmental Protection Agency (EPA). And each one of these agencies examines these products to ensure that they are safe for release in the general environment, as well as safe for consumption by humans or by animals. The process that these regulatory agencies follow is essentially the same as that followed in the case of human or animal drugs that are approved or pesticides that are approved for use on crops.

Q: Consumer advocates, however, have raised concerns that some of these biotech products have not been adequately tested to evaluate such issues as allergenicity, environmental risks, and the accidental crossover to non-genetically modified plants, and do not address cultural considerations. What is being done to assure that regulatory authorities address these issues?

GALVIN: All new varieties -- before they are approved -- first have to undergo testing. And that testing involves actual planting in test plots. Then the test plots that are harvested are analyzed, and are tested to make sure they are safe for consumption. The products are certainly tested with respect to safety for humans or animals. They are tested for allergenicity as well. There is a question as to what their long-term impact might be, especially on the environment. That issue was addressed in part by U.S. Agriculture Secretary Dan Glickman this past summer when he announced that USDA would continue ongoing tests on the long-term environmental impacts. With respect to the final point about cultural considerations, I concede that such considerations do not enter into the regulatory approval process here in the United States. In our view, it's basically up to consumers whether or not they want to purchase individual products.

Q: You just mentioned that we are going ahead with long-term analysis. Critics argue that we should not be moving ahead as quickly as we are until we have some of these long-term results.

What is your response?

GALVIN: Basically, the regulatory agencies involved believe that there is a sufficient body of scientific evidence in hand that demonstrates that these products are safe; otherwise, the products would not have been approved in the first place. As with any new technology, you never really know the long-term impact until you have had long-term experience with the product, the sort of experience that, unfortunately, you can only gain with additional time.

Q: Some environmental groups and elements in the media have used Cornell University preliminary research on the monarch butterfly and Bt corn to condemn the use of genetically engineered plants in agriculture. What are the implications of this research?

GALVIN: A number of scientists have commented on that study. They have pointed out that the Cornell research was a laboratory test; it is not at all certain that the findings from that test could be replicated in the actual environment under which this particular variety is used. Indeed, even the Cornell scientists who were involved in that study have said essentially the same thing, that it is not clear really how relevant the results are in terms of real-life experience.

Q: Some countries have begun arguing for the mandatory labeling of genetically engineered food imports. What is the current U.S. position on labeling?

GALVIN: Our position is that voluntary labeling is appropriate. With respect to mandatory labeling, some of the countries that currently support it are also struggling with the operational details of just how to implement it. The best example, of course, is the European Union (EU), where they announced their mandatory labeling policy one year ago but, even to this day, are struggling with such implementing details as where to set a tolerance level. That tolerance level would allow a certain amount of GMO (genetically modified organism) product to be included in a variety that was otherwise considered non-GMO. Apparently they are thinking of setting that tolerance level at about 1 percent. A related question is what testing procedures are going to be sanctioned in determining the presence of genetically modified varieties, and the EU has still not decided that issue. A third major question is who is actually going to do the testing? Will it be government authorities, or will the private sector be allowed to do the testing and self-certify? Those are all questions that the EU continues to struggle with, and, as I have said, they have been wrestling with the issue for more than a year now.

Q: What would be the implications for U.S. exports of a GMO tolerance level at 1 percent?

GALVIN: The implications would be significant. And not just for U.S. exports, but for exports of GM products by a whole host of countries that currently produce them, including Argentina, Canada, Australia, and even countries in the EU, where this past year, for example, more than 20,000 hectares (49,400 acres) were planted to certain GM corn varieties. So, I think it is going to be a major issue for a number of countries. Frankly, I think the EU is going to find that the 1 percent tolerance level is a very, very difficult level to meet and presents the potential for

substantial trade disruptions as a result.

Q: How do you balance the need for intellectual property protection, such as patents, in the development of biotechnological products, such as wheat germplasm, with the rights of farmers in the developing world to take advantage of this new technology?

GALVIN: I think you balance it by making sure that there continues to be a substantial government role in research and also in germplasm preservation. Related to that, there is an ongoing need for the role that certain international agencies play in obtaining this germplasm and providing it to countries that could not develop it on their own. To me, whether one is talking about the latest varieties of conventionally produced seed or the latest varieties of the products of genetic modification, we are faced with the question of who is going to have access to the latest seeds. And I think it really requires a continuing government role or a continuing role on the part of international organizations like the United Nations to make sure that at least a portion of this research is done in the public sector and that at least some of the germplasm remains in the hands of government authorities so that it can be provided to these countries.

Q: If you have a biotech product that has been patented by a private company, how can these rights be transferred to an international institution?

GALVIN: In the case of a specific variety that has been patented by the private sector, you would not be able to transfer it unless that company was to provide some sort of license under its patent. That's why it important that governments continue to stay involved in the basic research and development of other varieties that also offer potential benefits to farmers.

Q: How much farmland is currently planted to genetically engineered varieties worldwide?

GALVIN: The best information we have for worldwide plantings is for 1998, and for that year the figure is about 29 million hectares (71.63 million acres) in total. Most of that would be in the United States. We are also assuming that biotech acreage increased in 1999. We know for a fact that occurred in the United States. Indeed for this year, we are currently projecting that one-third of our corn (maize) acreage, half of our soybean acreage, and about 60 percent of our cotton acreage is planted to biotech varieties.

Q: Is the United States the only industrial country that has developed genetically engineered products? If not, then who are the other key players in the global marketplace and which GMO products have they developed?

GALVIN: The United States is not alone in developing new GMO products or in offering them for commercial production. In fact, it's quite the opposite. As I mentioned earlier, we've seen GM varieties planted in a number of countries -- the United States, Argentina, Canada, Australia, Spain, and France, just to name a few. In addition, even in the United States it's not just U.S. companies that are involved in the field. In fact, there is a substantial presence of EU companies.

For example, AgrEvo, a German company, and Novartis, a Swiss company, both have very active biotechnology programs here under which they've offered commercial varieties such as different genetically modified corn and soybean varieties. And even though the EU regulatory approval system for biotech crops right now has ground to a virtual halt, fully one half of the applications for biotech crops currently pending in the EU approval pipeline are applications sponsored by European companies.

Q: Are these European companies being stymied in what they can do, or is there any competitive advantage being given to them relative to U.S. companies in Europe?

GALVIN: I don't think there is any competitive advantage being given to them. In fact, I think part of the reason we've seen some research efforts moving to the United States is because the regulatory climate in Europe frankly is so hostile toward the technology. I think that is causing some concern among these European companies as well as among European farmers, who worry that they may lose a technological edge. And I think it's also of some concern to policy-makers generally in Europe because, as you know, Europe is struggling with unemployment rates that are typically far higher than in the United States, sometimes two to three times higher.

Q: Is it feasible to segregate genetically engineered products for export from "GMO-free" products, as some trading partners have suggested?

GALVIN: It's very, very difficult if one insists on 100 percent certainty with segregation. Yes, an attempt can be made to segregate crops just as we currently try to segregate organically grown crops from conventional crops. But as we've seen in the case of organically produced crops, those crops typically command a premium in the marketplace. And, in fact, farmers generally command a premium for growing those crops because of the additional cost of producing them, as well as the additional cost of sorting, segregating, and handling those commodities through the marketplace. Certainly, if you look at how our major crops -- corn, soybeans, and the like -- are produced and the way they are harvested and marketed, there is always potential for at least the inadvertent mingling of conventional and biotech varieties. And that is why those who are insisting on very low tolerance levels to guard against co-mingling are going to find from a practical standpoint that that is nearly impossible.

Q: How does the U.S. government determine that biotech agricultural products banned by other countries are not reaching export channels?

GALVIN: The government does not play a formal role in that area. What we have done is to work with the companies involved to encourage them to put in place a system for channeling the varieties that have not been approved for export into domestic consumption, especially into domestic livestock consumption, so that we can be somewhat more assured that the products are not finding their way into processed commodities here in the United States.

Indeed, those companies that currently offer for sale certain varieties not yet approved in Europe

have put in place a rather extensive channeling system that begins when farmers purchase the seed before planting. A farmer is asked to sign a statement acknowledging that the variety in question has not yet received all the necessary international approvals; in the course of the growing season, the farmer is sent letters reminding him that necessary approvals have not yet been granted and providing him with additional information on where he can market those unapproved varieties. For example, the companies might provide a list of local livestock feeding operations or local grain elevators that might be able to sell the product to livestock facilities in the United States.

Q: How will biotechnology issues be addressed in the upcoming World Trade Organization (WTO) ministerial in Seattle?

GALVIN: It is not at all clear yet just how they are going to be addressed, or even if they are going to be addressed. There are a number of proposals on the biotech issue. From the standpoint of the United States, we submitted a proposal in Geneva a few weeks ago that focuses very simply and directly on the issue of the regulatory approval processes that may be put in place in each country. We certainly don't question the right of any country to have its own review and approval process in place. But what we have said is that whatever process a country has, it should be transparent, predictable, timely, and science based. Those are four principles that are reflected in the current U.S. regulatory system, and we believe that other countries would do well to accept them as a part of their regulatory systems as well.

Q: What is the U.S. view about creating a WTO study group on biotechnology?

GALVIN: We have not yet said that we support a study group approach. That is an approach that Canada has suggested. We have said that we would prefer to go directly into negotiations on the issue, but only along the lines of the targeted concept that I just outlined -- one that is rather narrowly focused on the issue of regulatory approvals and how those approvals should be conducted. It's conceivable that other countries may suggest that biotech be addressed in a much more wide-ranging way, a way that perhaps also addresses labeling and other related issues. The United States has not endorsed that broader approach.

Q: There has been a lot of misperception about the terminator gene that prevents the germination of seeds and whether the United States has contributed to the development of the seed. Can you comment?

GALVIN: As you know, about 10 days ago Monsanto announced that they have no plans to ever commercialize the technology, and I don't know of any other entity that currently plans to use it.

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